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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/203,768	12/02/98	WATKINS J	P-IX-2947

HM12/0203

CATHRYN CAMPBELL
CAMPBELL AND FLORES
4370 LA JOLLA VILLAGE DRIVE
SUITE 700
SAN DIEGO CA 92122

EXAMINER	
HELMS,L	
ART UNIT	**PAPER NUMBER**
1642	6

DATE MAILED: 02/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/203,768	Watkins et al
Examiner	**Group Art Unit**
Larry R. Helms Ph.D.	1642

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *NONE* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-46* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-46* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ NOTICE TO COMPLY WITH SEQUENCE REQUIREMENTS

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to an antibody comprising CDRs from SEQ ID NO:2 or SEQ ID NO:4, which the specification teaches is specific for the LH11238 antigen (see page 16, lines 10-21), classified in class 530, subclass 388.85.

II. Claims 7-9 and 16-18, drawn to an isolated polynucleotide, classified in class 536, subclass 23.1.

III. Claims 10-15, drawn to an antibody comprising CDRs from SEQ ID NO:6 or SEQ ID NO:8, which the specification teaches is specific to LH13 antigen (see pages 16, lines 23-32 and page 17, lines 1-2), classified in class 530, subclass 388.85.

IV. Claims 19-23 and 34 in part, drawn to an antibody produced by the cell line H1140, which the specification teaches is specific for the antigen H1140 (see page 17, line 30), classified in class 530, subclass 388.85. If this group is elected claim 34 will be examined to the extent it reads on an antibody specific to the antigen H1140.

V. Claims 24-28 and 34 in part, drawn to an antibody produced by the cell line H2420, which the specification teaches is specific for the H2420 antigen (see page

17, line 30), classified in class 530, subclass 388.85. If this group is elected claim 34 will be examined to the extent it reads on an antibody specific to the antigen H2420

VI. Claims 29-33 and 34 in part, drawn to an antibody produced by the cell line H935, which the specification teaches is specific for the antigen H935 (see page 17, line 30), classified in class 530, subclass 388.85. If this group is elected claim 34 will be examined to the extent it reads on an antibody specific to H935.

VII. Claims 35-36, drawn to a method of reducing neoplastic cell proliferation comprising administering an antibody specific to LH11238, classified in class 424, subclass 156.1.

VIII. Claims 37-38, drawn to a method of reducing neoplastic cell proliferation comprising administering an antibody specific to LH13, classified in class 424, subclass 156.1.

IX. Claims 39-40 in part, drawn to a method of reducing neoplastic cell proliferation comprising administering an antibody produced by cell line H1140, classified in class 424, subclass 156.1. If Group IX is elected the claims will be examined to the extent they read on administering an antibody produced by cell line H1140.

X. Claims 39-40, drawn to a method of reducing neoplastic cell proliferation comprising administering an antibody produced by cell line H2420, classified in

class 424, subclass 156.1. If Group X is elected the claims will be examined to the extent they read on administering an antibody produced by cell line H2420.

XI. Claims 39-40, drawn to a method of reducing neoplastic cell proliferation comprising administering an antibody produced by cell line H935, classified in class 424, subclass 156.1. If Group XI is elected the claims will be examined to the extent they read on administering an antibody produced by cell line H935.

XII. Claims 41-42, drawn to a method of detecting a neoplastic cell in a sample comprising contacting the sample with an antibody specific to LH11238, classified in class 435, subclass 7.1, for example.

XIII. Claims 43-44, drawn to a method of detecting a neoplastic cell in a sample comprising contacting the sample with an antibody specific to LH13, classified in class 435, subclass 7.1, for example.

XIV. Claims 45-46 in part, drawn to a method of detecting a neoplastic cell in a sample comprising contacting the sample with an antibody produced by a cell line H1140, classified in class 435, subclass 7.1, for example. If Group XIV is elected the claims will be examined to the extent they read on an contacting with an antibody produced by H1140.

XV. Claims 45-46 in part, drawn to a method of detecting a neoplastic cell in a sample comprising contacting the sample with an antibody produced by cell line H2420,

classified in class 435, subclass 7.1, for example. If Group XV is elected the claims will be examined to the extent they read on contacting with an antibody produced by H2420.

XVI. Claims 45-46 in part, drawn to a method of detecting a neoplastic cell in a sample comprising contacting the sample with an antibody produced by cell line H935, classified in class 435, subclass 7.1, for example. If Group XVI is elected the claims will be examined to the extent they read on contacting with an antibody produced by H935.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups 1-VI represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The polynucleic acid of Group II, and the antibodies of Groups I, and III-VI are all structurally and chemically different from each other. The polynucleotide is made by nucleic acid synthesis while the antibody is raised by immunization. In addition, the antibodies of Groups I and III-VI are all different in that each antibody is specific for a specific antigen as evidenced in the specification (see above). The antibodies were produced by different immunizations (see Table 2, page 45), the antibodies are structurally and functionally different (see Table 3, page 49), the antibodies LH13 and LH 11238 have different immunoreactivity (see Table 4, page 51), and the antigens of LH13 and LH11238

have different localization (see Examples IV and V and VI and VII). Therefore, one skilled in the art would reasonably conclude that the antibodies are different and bind to different antigens. Also, one skilled in the art would conclude that since the antibodies bind to different antigens the antibodies are all structurally different in that each would have a different and specific antigen binding region consisting of the CDRs in the antibodies.. Furthermore, the polynucleotide can be used for hybridization screening and the antibody can be used to immunopurify the specific antigen, for example. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I-VI are patentably distinct.

The methods of Inventions VII-XVI differ in the method objectives, method steps and parameters and in the reagents used. Invention VII recites a method of reducing neoplastic cell proliferation comprising administering an antibody produced by LH11238; Invention VIII recites a method of reducing neoplastic cell proliferation comprising administering an antibody produced by LH13; Invention IX recites a method of reducing neoplastic cell proliferation comprising administering an antibody produced by H1140; Invention X recites a method of reducing neoplastic cell proliferation comprising administering an antibody produced by H2420; Invention XI recites a method of reducing neoplastic cell proliferation comprising administering an antibody produced by H935; Invention XII recites a method of detecting a neoplastic cell in a sample comprising contacting the sample with an antibody specific to LH11238; Invention XIII recites a method of detecting a neoplastic cell in a sample comprising contacting the sample with

an antibody specific to LH13; Invention XIV recites a method of detecting a neoplastic cell in a sample comprising contacting the sample with an antibody specific to H1140; Invention XV recites a method of detecting a neoplastic cell in a sample comprising contacting the sample with an antibody specific to H2420; Invention XVI recites a method of detecting a neoplastic cell in a sample comprising contacting the sample with an antibody specific to H935. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions VII-XVI are separate and distinct in having different method steps and different endpoints and are patentably distinct.

Inventions I and (VII and XII); III and (VIII and XIII); IV and (IX and XIV); V and (X and XV); and VI and (XI and XVI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of groups I, and III-VI can be used in a materially different process such as immunopurification of the specific antigens in addition to the methods of Groups VII-XVI.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

5. A telephone call was made to David Gay on February 2, 2000 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Sequence Requirements

7. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

8. Any questions regarding compliance with the sequence rules requirements specifically should be directed to the departments listed at the bottom of the Notice to Comply.

9. APPLICANT IS GIVEN THE TIME ALLOTTED IN THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.R.F. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D., whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

JULIE BURKE
PRIMARY EXAMINER

Application No.: 09/203768

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other: _____

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE